### Frequently Asked Questions

Alzheimer's Disease Research Awards Request for Applications (RFA) #18-10612

(Source: Informational Call on Friday, January 11, 2019, 10:00 AM – 12:00 PM)

1. Question (Q): Is the Letter of Intent a screening step to gain approval for submitting a full proposal on Feb. 8 or whether the LOI is just one of the submission requirements and approval for submission of a full proposal on Feb. 8 is not required?

Answer (A): Please see RFA Page 9, V. Application Requirements, 1. The LOI is a submission requirement and helps the Program gauge the # of applicants.

2. Q: The RFA states that interventions, not clinical trials are okay. Can you define what is meant by a clinical trial?

A: Please see the RFA Page 6, III. Objectives # 5, "Please note that this Request for Application does not accept applications proposing clinical trial(s)." "In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention." Standard of practice research is allowable.

3. Q: The RFA states that the Primary Investigator (PI) must be located in CA, is that the same for the collaborators?

A: Yes. Please see RFA Page 8, C. Applicant Eligibility, "Applicants must be California-based, and all relevant project activities must take place in California. Institutions and principal investigators participating in a Consortium Research Award are also subject to these requirements." The primary applicant and all other associated co-applicants and subcontractors MUST be located in California.

4. Q: Do all manuscripts developed for submission for publication need to be submitted to the CA Alzheimer's Disease Program (ADP) prior to submission?

A: Yes. Please see RFA Page 15, H. Publications, Presentations or Printing of Reports, "Grantees shall notify the ADP of all publications, presentations, printed reports, and resulting research findings created for this project both during the grant period and for a period of six years after the grant period." If a grantee is intending on publishing research results, then the grantee should notify the ADP before submission for publication as well as submit a copy of the manuscript for documentation and archival purposes.

5. Q: I still don't know what is meant by "The Grantee must include the ADP as a peer reviewer on any publication by emailing the ADP at <u>AlzheimersD@cdph.ca.gov"</u>. Does this just mean that the grantee is expected to notify ADP as soon as an article is accepted for publication?
A: Yes. Please see RFA Page 15, H. Publications, Presentations or Printing of Reports, "The Grantee must include the ADP as a peer reviewer on any publication by emailing the ADP at

#### AlzheimersD@cdph.ca.gov."

The ADP would like grantees to be proactive in letting the ADP know as soon as an article is accepted for publication as well as serving as a peer reviewer on any submitted publication.

#### 6. Q: What is the purpose of such review?

A: ADP is added as a reviewer to optimize the intent of authorizing legislation pursuant to AB 609 (Nestande, 2014), "... require the grantee to provide for public access to any publication of a department-funded invention or department-funded technology, as specified, including ensuring that electronic version of the peer-reviewed manuscript is available to the department on an appropriate publicly accessible database approved by the department, to be made publicly available not later than 12 months after the official date of publication." See <u>Legislation</u> for full text.

#### 7. Q: Is it okay to propose use of national or international data sets for this RFA?

A: Yes. This is allowable, however, please keep in mind the diverse population of our great state when selecting data sets to ensure comparability.

### 8. Q: Define the use of consortium? Could we include the City of Oakland as part of a consortia?

A: Yes. Please see RFA Page 8, C. Application Eligibility, "Applicants must be California-based, and all relevant project activities must take place in California. Institutions and principal investigators participating in a Consortium Research Award are also subject to these requirements." Consortium is an association or a combination, as of businesses, financial institutions, or investors, for the purpose of engaging in a joint venture.

# 9. Q: Reference style – which style do you want us to use for the references? Where do you want us to put them? Do they count against the page count maximums?

A: There is no dictated reference style. Please select on and remain consistent throughout the RFA. The reference page(s) may be placed at the end of the narrative section (Body of Proposal, Attachment D) and do not count towards the page count maximum.

# 10. Q: Scope of the projects – what are the intentions of the individual vs. consortia projects? What are the expectations at each level (re: size of project and number of participants)? Pilot projects or full robust trial project?

A: Please see RFA Page 6, III. Objectives - "Applications for feasibility studies, pilot projects, and startup grants are encouraged, as are applications that expand the scope of ongoing research activities related to the area or topic of this RFA, or which entail multidisciplinary or collaborative research." Therefore, the scope of the research project is at the discretion of the applicant and their partners.

#### 11. Q: Is there a format to the Letter of Intent (LOI)?

A: There is no format to the LOI. Please see RFA Page 9, V. Application Requirements, 1. The LOI must include research topic area.

### 12. Q: Can applications include more than one topic area?

A: Yes, applications can include multiple topic areas or multiple submissions in individual topic areas.

### 13. Q: Are prior-funded grants available to the public?

A: Yes, previously awarded grants are listed by category and institution on our **Alzheimer's Disease Program** website.

## 14. Q: What are the limits to potential purchase of lab supplies and/or software or lab testing services from other states in the US or internationally?

A: If a purchase is with an out-of-state supplier, the applicant must submit a justification for review and approval, thus, follow California state purchasing guidelines.

# 15. Q: We would like to know if we can purchase reagents to be used for plasma assays processed in an international lab, since it is the only lab doing this type of work. We would not pay for the work to be done, just the reagents (supplies) to be used.

A: Yes, and include justification. Please specify how this process adheres to sound scientific principles and ethics.

### 16. Q: Can an individual participate in more than one application (individual and consortium?)

A: Yes. Please see RFA Page 7, IV. Application Information, B. Categories of Awards, "Two categories of funding are available: Independent Investigator Awards and Consortium Research Awards. Applicants may apply in one or both categories." NOTE: Such an individual applicant may only be paid up to the 100% full time equivalent across all grant applications.

### 17. Q: Can there be multiple grant applications from one institution?

A: Yes.

#### 18. Q: What is the program's definition of "institution?"

A: An institution is an established organization or corporation.

### 19. Q: Is there a cap for the salaries of the investigators?

A: Yes, salary cap is used to optimize the use of California grant funds. The <u>salary comparison the State</u> uses is set by U.S. Department of Health and Human Services.

## 20. Q: Any exclusions on allowable costs such as graduate students tuition that are working on the grant?

A: Graduate student participation is encouraged and can be incentivized through salary or stipends but not through tuition.

#### 21. Q: Are submitted reviewers limited to CA or beyond CA?

A: Please see RFA Page 40, Reviewer Recruitment – "please identify six (6) potential reviewers residing in the United States that are qualified."

# 22. Q: Principal investigators with co-investigators on the same grant considered an individual or consortia? (e.g., UCD grant with co-investigators at other sites?)

A: Applicants would be considered an individual as long as all applicants belong to the same academic institution (e.g., sites within University of California (UC) Davis would be an individual application, but if sites from UCD, UCSF, and UC Merced applied jointly then the application would be considered a consortia).

# 23. Q: A 501c3 organization is working with UCSF. Would it be OK for the majority of funding to go to the 501c3 and then to UCSF as a subcontractor? (501c3 as primary applicant – is this allowed?)

A: No. Please see RFA Page 8, C. Applicant Eligibility, "Investigators must be eligible to hold Principal Investigator status at an academic institution in the State of California, if applying as an academic institution." A 501c3 could be a subcontractor or member of a consortia.

- **24.** Q: Budget question: are stipends for participants an allowable use of funds for these grants? A: Yes.
- 25. Q: Are matching funds pro/con or neutral with respect to this application? Would there be any impact on the application? Would you want to see matching funds represented in the budget?

  A: No impact on the application if the applicant has matching funds or not. Matching funds should be detailed to clarify if aims of application would not be completed solely with state funds.
- 26. Q: For Federal funds received should we include a section for "other support" funds? If so where should we put it?

A: Include in the budget with additional columns to identify any matching or other source of supporting funds.

27. Q: Collaborators: are there a limit to the number of collaborators for consortia?

A: No limit stated, but one limit is the budget amount and the ability to successfully incorporate any un-funded collaborators. Please see RFA Page 7, IV. Application Information, B. Categories of Awards – "grantee institution and two (2) or more participating institutions."

28. Q: Is the out of state restriction due to funding source?

A: Yes, these grants are paid through California income tax dollars.

29. Q: Do subcontractors have to pay indirect cost on a percentage of the first \$25k (like an NIH grant?) or a blanket 8%?

A: No. General administrative costs of up to 8 percent of the total grant are paid, this is a cumulative total of grantees and sub recipients. Grantees are required to abide by the 8% indirect cost rate.

30. Q: When computing the indirect costs we understand that we are limited to 8% of total costs. However, we will give our subcontracts 8% F&A on their direct costs. Hence, the amount that will be entered for each subcontract will be the combination of their total direct costs plus 8% F&A, please see below form. The question is what to do when computing the total costs F&A. Shall we exclude the subcontracts' costs? (since their F&A will be included it in their costs). If we were to use the total costs as a base for computing our F&A, there will be double F&A charges to the subcontract costs. Please let us know what to do.

A: Please see response to Question 29.

31. Q: Can we pay community practitioners (MDs) for patients that they see as part of the grant project (not paying them for patient care but for the data from the patients)?

A: Yes, you may pay for data via community practitioners, but must adhere to any Institutional Review Board and Health Insurance Portability and Accountability Act requirements.

32. Q: What are the plans for funding beyond 2020?

A: Any future RFA and funding opportunities will be based on future funding availability and unobligated funds. Please see RFA Page 7, IV. Application Information, A. Funding Scope and Time

Period, "Applications may be submitted for a five-year duration."

33. Q: Letter of support for collaborators who are not the PI (same or not the same institution)?

A: Please see Attachment 1 instructions on Page 10 of the RFA, "Consortium applicants must complete Attachment A1. Please include Letter(s) of Commitment from collaborating institutions and attach to A1. Failure to include the Letter(s) of Commitment will be viewed as non-responsive and the application may not be considered for funding."

34. Q: Reviewers: Are nomination of 6 reviewers for one application only or for use across all the applications?

A31: Yes, nominated reviewers are considered for use across all applications.

- 35. Q: In the innovation section, the prompt asks to "Summarize novel findings to be presented as preliminary data in the Approach section." -- Could you please explain this quote further?

  A: Please summarize the elements of the one page innovation section in the Approach Section. Please see RFA Page 12, 4. "The purpose of the approach section is to describe how the research will be carried out. The research design and methods section should include the following: PI's preliminary studies, data, and experience relevant to the application and the experimental design; the overview of the experimental design; a description of methods and analyses to be used to accomplish the specific aims of the project; a discussion of potential difficulties and limitations and how these will be overcome or mitigated; expected results, and alternative approaches that will be used if unexpected results are found; and a projected sequence or timetable (work plan)."
- 36. Q: In the RFA it is stated that a total of \$3 million per year is available for funding and that single investigator grants can propose up to \$600,000 per year while multi-campus projects can propose up to \$1 million per year. Given these numbers I am curious about what type of projects the program is likely to fund in terms of scope. In other words, are you looking to fund 2-3 large projects (inclusive of both categories) or more interested in funding a larger number of smaller projects?
  A: The number of grants, grant types and scope will be determined by the application pool. We anticipate it will be competitive at both the individual and consortia levels.
- 37. Q: Will this RFA fund smaller scale projects (under \$50,000)? A: Yes.
- **38.** Q: Is there a minimum funding amount requested to be considered? **A:** No.